NEBRASKA
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DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH PROTECTION
**COMMERCIAL FEED PROGRAM**

# Firms That Manufacture Feeds Guidance

Your answers indicate that your firm is engaged in activities that will require it to be in full compliance with 21 CFR 507. Your facility should pay particular attention to Subpart A (General Provisions), Subpart B (Current Good Manufacturing Practices), Subpart C (Hazard Analysis and Risk-Based Preventive Controls), and Subpart F (Requirements Applying to Records That Must Be Established and Maintained).

A facility that is required to comply with Subpart A should be aware of the General Provisions as outlined in that portion of the PCAF Rule. Important areas of focus include definitions used throughout the rule (Section 507.3), requirements for Qualified Individuals who handle animal food (Section 507.4), and various firm exemptions (Section 507.5).

Of the General Provisions, Section 507.4 is likely to be the most important area of concern for a firm of this type. This section deals with firm management's responsibility to ensure that all employees handling animal food are appropriately trained for their jobs. An appropriately trained employee is defined as a Qualified Individual in Section 507.3 of the rule. The qualifications can be training, education, experience or any combination of the three. The rule also states that supervisory personnel are to be responsible for the training and its documentation.

Both 21 CFR 507 Subpart B and Subpart C are complex portions of the rule that will have the largest number of factors your firm should consider to be in full compliance. Subpart B outlines all the areas that require a firm's attention to remain in compliance with the Current Good Manufacturing Practices (CGMPs) portion of the PCAF Rule. The areas of concern listed in Subpart B are Personnel, Plant and Grounds, Sanitation, Water Supply and Plumbing, Equipment and Utensils, Plant Operations, as well as Holding and Distribution. Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals breaks each area down and describes ways you can achieve and maintain compliance. The last portion of that document includes a Self Assessment Tool which you can use to compare your facility's practices with FDA's expectations.

Subpart C deals with a Hazard Analysis and Food Safety Plan. According to your answers your firm manufactures feed for animals. That can include a large number of activities and varying degrees of complexity. The important aspects to remember from this subpart are that you have identified individuals who will be responsible for developing your Hazard Analysis and Food Safety Plan and then you have identified any hazards in your facility and ways that you mitigate those hazards. Towards the end of this guidance you will find a link to more resources that will provide some direction through this process.

Another section which applies to firms that manufacture animal feed is documentation records. Rules regarding recordkeeping are outlined in Subpart F. Warehouses that hold packaged animal feed should consider being aware of requirements applying to records (Section 507.202) and requirements for record retention (Section 507.208). General requirements for records include items such as they must be originals or true copies, be accurate, indelible and legible, as detailed as necessary, and include the identity of the facility, date, and identity of person performing the documented activity. Regarding record retention, all records are to be kept at the facility they were prepared for at least two years unless indicated otherwise.

These are some key points to remember to ensure that your facility remains in compliance with these new rules. For further information, you may reference 21 CFR 507 here or you can view Guidance for Industry #235: Current Good Manufacturing Practices for Food for Animals here.

Developing a Food Safety Plan can seem like a daunting task. There are many factors to consider and it's not always clear what is considered a hazard. Start by creating lists of each kind of ingredient your facility uses and the types of products you handle or manufacture. Once you've done that you can create a process flow diagram that will show how product moves through your facility. This will help you determine each place where a hazard may be introduced.

Follow the link below to enter this data into a tool the Nebraska Department of Agriculture has designed to help with identifying hazards.

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